AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings replaces all figures in the present application (FIGS. 1, 2A – 2I, 3A – 3J, and 4A – 4G). The drawings have been updated to conform with the formal drawing requirements of 37 C.F.R. 184(p).

Attachment: Replacement Sheets

REMARKS

Claims 1 – 18 are pending in this application. Claims 11 – 14 and 18 are currently amended. Support for amended claims 14 and 18 is found, for example, in FIGS. 3B – 3J. Amendments to claims 11 – 13 are cosmetic in nature and correct minor grammatical/typographical errors.

The specification has been modified to correct minor grammatical/typographical errors.

In addition, replacement drawings have been submitted to comply with the Office's formal drawing requirements.

Rejection of Claims 14 and 18 Under 35 U.S.C. §102(e)

Claims 14 and 18 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Published Application 2003/0236555 (hereinafter "Thornes").

The method of claim 14 of the present application recites (in part):

> ***wrapping the second end of the band around side edges of a bone***;
> tightening the band to ***secure*** both sides of the bone fracture together . . . .

As best shown in FIGS. 3B – 3J, the method recited by claim 14 comprises securing a first end of a band to a bone (as shown in FIG. 3E, for example), wrapping a second end around the sides of the bone (as shown in FIG. 3G, for example), and securing a second end of the band to the bone (as shown in FIGS. 3I and 3J, for example).

Thornes describes a method for "fixation of ankle syndesmosis tibiofibular diastasis," in which an apparatus is provided that includes first and second buttons connected by a suture. (Thornes' claim 5.) In this method, through holes are drilled in the fibula and tibia, and the first button and a portion of the suture are threaded longitudinally through the holes. (*Id.*) Once the first button has been threaded completely through the holes, the suture is tightened to compress the bones together (Thornes FIGS. 3 – 7.)

The method recited by claim 14 of the present application differs significantly from the "needle and thread" method described in Thornes. In the method recited by claim 14, a band is wrapped around the sides of a fractured bone, and each side of the fracture is pushed or squeezed toward the other, thus closing the fracture. In the method described in Thornes, the opposing

sides of the fibula (26) and tibia (28) are compressed together as the excess suture is pulled through the through hole (18 and 30) of each bone, thus abutting the bones to one another. (Thornes FIGS. 3 – 7.) However, the bones are not *secured* to one another, nor are they immobilized, as would be necessary for the repair of a fracture. (See Thornes ¶ [0005] ("It is an object of this invention to overcome the problems associated with the prior art, whilst *permitting normal physiological movement* of the fibula relative to the tibia.") (emphasis added).) Thus, the bones are allowed to move relative to one another. In the device recited by claim 14 of the present application, this is not the case. At least because Thornes does not describe each and every limitation of the device recited by claim 14 of the present application, Applicants respectfully request withdraw of the rejection of claim 14 and all claims depending therefrom.

Rejection of Claims 1 – 6, 9, 12, and 13 Under 35 U.S.C. §103(a)

Claims 1 – 6, 9, 12, and 13 stand rejected under 35 U.S.C. § 103(a) as allegedly being rendered obvious by U.S. Patent 4,792,336 issued to Hlavacek et al. (hereinafter "Hlavacek") in view of U.S. Published Application 2002/0058966 (hereinafter "Tormala"). Applicants respectfully traverse this rejection.

As the Examiner is well aware from the recent Supreme Court decision in KSR v. Teleflex, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l. Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." Id. Furthermore, "'[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" Id. (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)); see also M.P.E.P § 2143.01(IV). In the present case, Examiner has provided no such reasoning.

Additionally, the combination or modification cannot render the prior art unsatisfactory for its intended purpose. In re Gordon, 733, F.2d 900 (Fed. Cir. 1984); M.P.E.P. § 2143.01(V). Also, in order to make a *prima facie* case of obviousness, the proposed combination or

modification cannot "change the principle of operation of the prior art invention being modified." M.P.E.P. § 2143.01(VI).

Hlavacek describes a "ligament or tendon implant device" used to repair or augment a ligament. (Hlavacek col. 8 lines 55 – 59, claim 1.) The specification does not describe precisely how the implant device is used or how it is secured in the applied position, only mentioning briefly that the needles may be used for attachment to soft tissue in certain applications. (Hlavacek col. 8 lines 59 – 63.) In fact, the specification is largely devoted to describing the materials used to construct the implant device and the methods of construction rather than the device's functional aspects or other structural aspects.

Tormala describes a device used to repair a tear in a tissue. (Tormala, ¶ [0011].) The device is "designed to compress the tear," is "shot totally inside [the] tissue," and "hold[s] the ruptured edges together." (Tormala, ¶¶ [0013] & [0014] (emphasis added).) This device is used independently of any band system and is designed to pull the two sides of a torn or fractured tissue together from within the tissue to repair the tear, as most clearly shown in FIGS. 11D and 14 of Tormala. The device has protrusions at its distal and proximal ends for securing the entire device inside the tissue, as the Tormala device is designed to transverse the tear.

No reasoning exists that would lead one of ordinary skill in the art to combine the teachings of Hlavacek with the device of Tormala. Both devices function as stand-alone implants, and Hlavacek does not have any problems or needs that Tormala would solve. No additional advantages are provided by adding the device of Tormala to the implant of Hlavacek. In fact, is unclear how the Tormala device could be applied to Hlavacek, as the Tormala device is designed to be inserted "totally inside [the] tissue," while Hlavacek's device is designed to have a substantial portion of the band remain outside of the bone. Furthermore, Tormala teaches that the device must be inserted at the tear so that the device can bridge both sides of the tear, as shown in FIGS. 11D and 14. The implant device in Hlavacek, in contrast, appears to knot around the bones and/or ligaments at several points, as show in FIG. 3 of Hlavacek. It is unclear how Tormala could be added to Hlavacek to further "prevent harm and encourage biocompatability between the patient and the device," (as explained by the Examiner) as each device already provides its own solution for fixing the device to bone or tissue. Thus, there is no reason that would lead one of ordinary skill in the art to combine the devices of Hlavacek and

Tormala. As the Examiner is aware, there must be some desirability in making the modification or combination. See In re Fulton, 391 F.3d 1195, 1200-01 (Fed. Cir. 2004); M.P.E.P. § 2143.01(I). Such desirability is lacking here.

In addition, using the Tormala device with the band system of Hlavacek would fundamentally change the functionality of both devices. The device of Tormala is designed to be inserted completely within the tissue (as evidenced by the protrusions located on its distal and proximal ends) and is not designed to act merely as a fastener for a band system. Instead, the Tormala device's intended purpose is to pull a tear in a tissue closed via insertion of the entire device into the tissue, bridging the tear. To use the Tormala device merely as a fastener to secure a band system would defeat this purpose and its principle of operation. Similarly, using the Tormala device to secure the Hlavacek device would fundamentally change the Hlavacek device's functionality, as the Hlavacek device is secured via knotting the band around bone or tissue (as shown in FIG. 3 of Hlavacek). Applying the Tormala device to the Hlavacek device would only create a hole or break in the band where the Tormala device is inserted. As the Tormala device is designed to be implanting entirely into the bone or tissue, not part of Tormala would remain attached to the Hlavacek band. This hole or gap in the band would significantly affect the Hlavacek device's ability to hold two bones or tissues together, thus defeating its purpose or principle of operation.

Accordingly, for at least these reasons, it would not have been obvious to one of ordinary skill in the art to combine the band system described in Hlavacek with the surgical fastener described in Tormala to arrive at the device recited by claim 1 of the present application. Applicants respectfully request withdraw of the rejection of claim 1 and all claims depending therefrom.

Rejection of Claims 10 and 11 Under 35 U.S.C. §103(a)

Claims 10 and 11 stand rejected under 35 U.S.C. § 103(a) as allegedly being rendered obvious by Hlavacek in view of Tormala, and further in view of Thornes. In addition to the rationale presented above, Applicants respectfully traverse this rejection for the following reasons.

Claims 10 and 11 recite a band system in which an end of the bioabsorbable band comprises a plate. As stated in paragraph [43] of the present application, the plates of these embodiments play a crucial role, as they "prevent[] the sternum from pulling apart, sliding, and bending, as a result of [various] forces." This is achieved through a greater surface area with which to anchor the locking system and/or support the area of the bone fracture, as shown in FIG. 4D. In addition, the use of a plate allows for the use of additional fasteners, thereby further securing the band system to ensure that the bone fracture remains closed.

The buttons described in Thornes, however are drastically different from the plates recited in claims 10 and 11 of the present application. The buttons described in Thornes include at least two apertures for receiving a suture, allowing the suture to slide freely through the apertures during tightening of the suture. (Thornes' claim 4.) The buttons are not secured to bone with fasteners. Additionally, the buttons are not located at the ends of the suture (as are the plates in claims 10 and 11), as the suture is able to slide through the buttons' apertures. Furthermore, in the implanted position shown in FIG. 7 of Thornes, the suture forms a loop around both buttons, making it difficult to even determine where the "ends" of the loop are located.

The plates recited by claims 10 and 11 of the present application, unlike the buttons in Thornes, do not comprise apertures for slidably receiving a suture or other flexible component. The buttons in Thornes are not located at the ends of the suture and do not secure the system to bone using fasteners, unlike the plates recited by claims 10 and 11 of the present application. For at least these reasons, Applicants respectfully request withdraw of the rejection of claims 10 and 11.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, and Applicants request that the above rejections be withdrawn. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees that are required in connection with the filing of this response are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

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